Exhibit 7

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC.	:	MDL NO. 2327
PELVIC REPAIR SYSTEM,	:	
PRODUCTS LIABILITY	:	
LITIGATION	:	

- - -

AND VARIOUS OTHER CROSS-NOTICED ACTIONS
CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

- - -

August 21, 2013

- - -

Continued videotaped deposition of DANIEL J. SMITH taken pursuant to notice, was held at the law offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, beginning at 9:12 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public for the State of New Jersey.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.951.5672 fax
deps@golkow.com

A. Correct.

Q. And laser cut mesh would be a new process. At this time in 2004 you didn't have any laser cut mesh. Right?

A. That would be correct.

Q. If you go to two pages forward, another blue circle that has issues or concerns with the product is "Particulate matter." Do you see that?

A. Two pages forward. I went backward, sorry.

Yes.

Q. It says the "Mesh is poor quality, falling apart. Blue mesh particles" are "very apparent. Blue mesh is 'Different' - stiffer. Sealed edges are better" and "safer." And it's "All part of" the "ROPE effect." Do you see that?

A. That's what someone has written, yes.

Q. Then under "Mitigation Strategies," I want to draw your attention to that, Mr. Smith. It states, "Risk/Benefits of sealing the edges - greater risk of erosion." Do you see that?

A. Yes.

Q. So sealing the edges of this product that is described here as falling apart and having

blue mesh particles fall off it, that would mean doing an ultrasound or a laser cut mesh. Correct?

A. It could, yes.

Q. And so your company understood as of 2004 that if you were going to provide a laser cut mesh in order to fix the mesh poor quality, as described here, then that would increase the risk of erosion. Correct?

MR. HUTCHINSON: Object to form. Counsel, this is a fact witness deposition.

THE WITNESS: I cannot answer that on behalf of whoever wrote this document.

BY MR. CARTMELL:

Q. Do you know if your company had that knowledge as of this time, that if you actually fixed the poor quality of the mesh that was falling apart by sealing the edges with laser cut mesh, if that would increase the risk of erosion?

MR. HUTCHINSON: Object to form.

THE WITNESS: It's my opinion this may not be an accurate statement.

BY MR. CARTMELL:

Q. You think the person who put this together was inaccurate; is that right?

A. No. I'm saying that whoever wrote

this said that might be a possible risk. I couldn't tell what they meant.

Q. We talked yesterday about the risk analysis process internally that your company was required to do by law in order to determine if your product was safe for patients' use. Correct?

A. Yes.

Q. I want to hand you what's been marked as Exhibits 261 and 262.

Let me hand you Exhibits 2161 and 2162, Mr. Smith.

MR. HUTCHINSON: We got them.

- - -

(Deposition Exhibit No. T-2161, Risk Management Report (Legacy) for TVT and TVT-O, Document Name (#): RMR-0000044, Revision: 1, Bates stamped ETH.MESH.01265223 through ETH.MESH.01265239, and Deposition Exhibit No. T-2162, Company Procedure for Medical Device Risk Management Plan, Document Name (#): PR602-003, Revision: 13, Bates stamped ETH.MESH.00070187 through ETH.MESH.00070211, were marked for identification.)

asking you questions about mesh fraying?

A. Yes.

Q. What is --

What do you interpret the phrase "mesh fraying" to mean?

A. It's due to the initial mechanically cutting of the gold standard TVT, small particles on the edges of the mesh had the potential to fall off of the mesh.

Q. Is there any clinical significance to mesh fraying?

A. From the information I've seen from our medical director, they do not feel that it's clinically significant.

Q. What did Ethicon do to address this mesh fraying issue?

A. There is an effort to laser cut the mesh and identify with it. However, both products, since they're clinically effective, both products are on the market today, both mechanically cut and laser cut.

Q. And, Mr. Smith, would you explain to the jury what mechanically cut is and what laser cutting is, please?

A. Since the -- all mesh is -- comes

from a roll and the -- of mesh, much like a roll of cloth, and it's then cut into strips the size for the mesh which is used, which we call the tape sometimes. And if it is mechanically cut, it's cut with something that would -- that may look like a paper cutter, whereas if it's laser cut, it's cut with a mechanical system using light from, like, a laser.

Q. And was laser cutting developed in response to the voice of the customer?

A. I would say yes. It started to look at ultrasonic cutting first, and we eventually settled on laser cutting as the best from an operational perspective.

Q. What is ultrasonic cutting or ultrasonic technology?

A. Ultrasonics is vibration, with vibration causing heat, and heat obviously used to sever the mesh.

Q. Are we on page 9?

A. I am.

Q. What is this?

A. This was an elongation chart to define the differences or similarities between laser cut and mechanical cut. And what this shows us is

that in the physiological range, which is the box, which is circled around the .25 or quarter inch elongation, that that physiological range, that the meshes are virtually identical. And the physiological range was established using the gold standard mechanically cut mesh, by taking that mesh and understanding at what point in the elongation or stretching of that mesh does the mesh no longer return to its original length. That's sometimes called the -- beyond its elastic limit or into its plastic limit. And that limit is defined by a value of about 164 grams.

And so what we have used at 164 as a number, and then there's studies that also represent -- the Lim study, which was a clinical trial which said that the urethra did not exert more than 50 grams of force on the mesh in laugh, cough and sneeze with a full bladder. So we kept the 164, knowing that the lower limit was 50 grams. And in that lower limit, as you can see by this chart, at 50 grams, the lines are identical. And at 164, which is the other side of the box, the lines are virtually on similar -- statistically similar.

Q. Mr. Smith, what do you mean by physiological range? Explain that for us, please.

A. The physiological range is a term saying that what -- the load of which the urethra physiologically in normal function, a woman's function, laugh, cough and sneeze, the load that the urethra would place on the mesh such that, you know, causing the mesh to elongate or stretch or move.

Q. Would that be another way of saying the amount of pressure put on specific body parts?

MR. CARTMELL: Objection, leading.

THE WITNESS: It would be the amount of pressure placed on the mesh if a mesh was placed midurethra, yes.

BY MR. HUTCHINSON:

Q. Did you prepare that document?

A. I was one of a few individuals in preparing this document.

Q. Do you remember plaintiffs' counsel asking you questions about Exhibit 2142?

A. Yes.

Q. Did he ask you any questions about this particular page?

A. I don't recall.

Q. Let's look at the next page, page 10.

It states, "Pull-out Force Comparison," at the top, "Average force in a Human

Cadaver." Do you see that?

A. Yes.

Q. What does this slide show us?

A. It was, again, some of the safety and efficacy data that we tried to put together, the 164, showing the physiological range. And it was looking at TVT SECUR in both the two positions, the hammock as well as the U, comparing it against Gynecare TVT and Gynecare TVT-O as controls. And what it indicated to us is that although there might be some differences with some products, they were all above, well above the 164 limit.

Q. So at the physiological limits, what is the difference, if any, between laser cut and mechanically cut mesh?

A. There is very -- there is none.

Q. Is that significant?

A. It's significant in the fact that the gold standard clinical data from mechanically cut mesh could be transferred over with the laser cut mesh as well.

Q. When you say transferred over, what do you mean by that?

A. I mean that the clinical studies earlier than laser cut mesh are relevant to the

laser cut mesh since it's the same mesh, made the same way, and the elongation properties of that mesh are identical, if not similar.

Q. Let's talk about clinical significance.

Did Ethicon do any testing to determine the clinical significance between mechanically cut mesh and laser cut mesh?

A. I'm not sure what all clinical studies were done with that. Postmarket, I know there was clinical studies done -- I'm sorry, premarket. I know there was clinical studies done postmarket.

Q. If you'll turn with me now to Exhibit 723.

Do you have that in front of you?

A. I do.

Q. And do you remember being asked questions about this document?

A. I do.

Q. If you'll look at page 0655, it's the third page of the document.

A. Yes.

Q. It states, "FDA Public Health Notification" at the top. Do you see that?

A. Yes.
Q. And to whom is this addressed?
A. It's basically addressed to all doctors or healthcare practitioners.
Q. And to your knowledge, does this public health notice sent by the FDA address mesh made by every company that manufactures mesh products?
A. Absolutely.
Q. So does it apply to the entire industry?
A. It does.
Q. And what is the date of this document?
A. October 20, 2008.
Q. In 2008, to your knowledge, how many mesh competitors did Ethicon have?
A. Numerous.
MR. CARTMELL: Objection. Object to the form.
BY MR. HUTCHINSON:
Q. If we look at the "Nature of the Problem" paragraph. Do you see that?
A. Yes.
Q. The first sentence, it reads, "Over

the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers."

A. It does.

Q. Does that ring a bell?

MR. CARTMELL: Object to the form.

THE WITNESS: I would have to agree with it.

BY MR. HUTCHINSON:

Q. Let's look at the first paragraph of this document.

What does the notification say about complications?

A. "This is to alert you" about "the complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse" as well as -- or -- "and Stress Urinary Incontinence" called SUI.

Q. What does the second sentence say?

A. "Although rare, these complications can" be serious -- "have serious consequences."

Q. And let's look at the second paragraph under "Nature of the Problem."

Do you see that?

A. Yes.

Q. What is noted to be the most frequent

complications?

A. "The most frequent complications included erosion through the vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel" and "bladder, and blood vessel perforation during insertion."

Q. And, Mr. Smith, are these risks that are associated with any pelvic floor surgery?

A. I would have to say yes.

Q. And were you and Ethicon aware of these risks from the first time you began working on TVT products?

A. I would say yes.

Q. Let's look at Exhibit 406 for a minute, please.

A. I'm sorry, 4 --

Q. 406. It's from yesterday.

A. Uh-huh.

Q. Do you remember being asked questions about this document?

A. I believe yes.

Q. If you'll look at the bottom, and Mr. Lawlor, if you can highlight this for me, please, the sentence that starts with the word "but." "But

the question keys and concerns." Do you see that?

It states, "But the key questions and concerns were about the safety of Ulmsten procedure. Indeed, it was broadly admitted that the use of any mesh through the vaginal route was associated with a high rate of complications, such as rejection/infection and urethral erosion." Do you see that?

A. Yes.

Q. Do you recall being asked questions by plaintiffs' counsel about that sentence?

A. I believe so.

Q. And does this document state the words "any mesh"?

A. Yes.

Q. So would that be limited to Ethicon's polypropylene mesh?

A. No.

Q. Did you author this document, Mr. Smith?

A. No.

Q. Do you have any idea what Axel Arnaud meant when he wrote the words "high rate of complications"?

A. I can only surmise that it was early

in the time frame of putting a new procedure from the Burch and there was some concerns.

Q. Let's look at Exhibit 353 for a minute, please.

MR. CARTMELL: I'm just going to object for the record to that statement and ask that it be stricken based on speculation.

BY MR. HUTCHINSON:

Q. Do you have that document in front of you?

A. I do.

Q. Do you remember being asked questions about that document?

A. I believe so, yes.

Q. And it says at the top, this is an e-mail from Axel Arnaud to Marty Weisberg, dated October 13, 2002. Do you see that?

A. Yes.

Q. And it's about soft Prolene. Do you see that?

A. Yes.

Q. And would you remind us again, please, who Axel Arnaud and Marty Weisberg are?

A. Axel Arnaud was a European medical director. And Marty Weisberg was also a US medical

director.

Q. Let's look at the sentence that states, "I just had a concern about your statement concerning Potential complications/Fistula & Erosions. This is a problem which arises rather commonly in practice even with polypropylene and it might be wise to be more elusive on this." Do you see that?

A. Yes.

Q. Do you remember being asked questions about that specific sentence?

A. Yes.

Q. Let's look at the last sentence. It states, "Also, as you said, when this" happens, "it is much less a problem with polypropylene meshes since it usually resolves with a partial excision and local care." Do you see that?

A. Yes.

Q. Did plaintiffs' counsel ask you any questions about that last sentence?

A. No, they did not.

Q. Let's look at Exhibit 2148, please.

MR. CARTMELL: I just object and move to strike the statements of counsel referring back to questions that plaintiffs' counsel asked you. I

think it's improper.

THE WITNESS: I don't know if I have that. 2148.

BY MR. HUTCHINSON:

Q. 2148?

A. Got it.

Q. And would you identify this document, please?

A. It's a clinical expert report signed by Marty Weisberg, senior medical director of Ethicon.

Q. Do you remember being asked questions about this document?

A. Yes.

Q. And for the benefit of the jury, what is a clinical expert report?

A. It's a document that's prepared by the medical director that is placed in the file and is a key document, primarily because the -- if there was no clinical trial needed, the clinical expert report serves as an expert opinion of the medical director.

Q. Did you sign off on this document?

A. I don't believe I would sign off on this document.

Q. Okay. And who did?
A. Marty Weisberg.
Q. Look with us, please, on page 241.
The second bullet point states, "Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation." Do you see that?
A. Yes.
Q. Do you remember being asked questions about the language in this bullet point under "Potential Complications"?
A. Yes, I do.
Q. Did you draft that language?
A. No, I did not.
Q. Would you be the appropriate person to handle questions about this language?
A. No, I would not.
Q. Who would be?
A. Medical director.
Q. Let's look at Exhibit 2149.
Do you have that in front of you, Mr. Smith?
A. I do.

- - -

(A discussion off the record occurred.)

- - -

BY MR. HUTCHINSON:

Q. Mr. Smith, I've handed you what's been marked previously as Exhibit 2149.

Do you recall being asked questions about this document?

A. I do.

Q. And this is an e-mail from Meng Chen at the top to Bryan Lisa, dated January 29, 2009; is that correct?

A. Correct.

Q. And if we look at the top of this e-mail and the e-mail "from" and "to" information below, did you send any of these e-mails?

A. Absolutely not.

Q. Did you receive any of these e-mails?

A. Absolutely not.

Q. Do you remember being asked questions about this document?

A. Yes, I do.

Q. Let's look at the first sentence under the original e-mail. It states, "Bryan: I have re-checked all three IFUs (for TVT-A, TVT-O and

TVT-S). Everyone has the language 'Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.'" Do you see that?

A. Yes.

Q. Do you remember being asked questions about that sentence?

A. Yes.

Q. Would someone in medical affairs be the more appropriate person to ask about the inflammatory response language in the IFU?

A. Yes.

MR. CARTMELL: Object to the form.

BY MR. HUTCHINSON:

Q. Would you turn to Exhibit 531 for me, please.

Do you have that document in front of you, Mr. Smith?

A. I do.

MR. CARTMELL: What's the exhibit number?

MR. HUTCHINSON: Exhibit 531, 531.

MR. CARTMELL: Thank you.

BY MR. HUTCHINSON:

Q. Would you identify this document, Mr. Smith?

A. It's a document that I was asked to -- about, and it's authored by Marty Weisberg.

Q. And what is the subject?

A. "Mesh Fraying for TVT Devices."

Q. Mr. Lawlor, could you highlight that as we go, please?

And the first few sentences of this document states, "This note to file will address complaints of TVT Tension-free Support for Incontinence mesh fraying during placement. Since introduction of the device in 2000, there have been a total of 58 complaints of fraying. Fraying is inherent in the design and construction of the product." Do you see that?

A. Yes.

Q. What does that --

And do you remember being asked questions about that?

A. Yes.

Q. What does it mean when this document states, the "Fraying is inherent in the design and construction of the" mesh?

MR. CARTMELL: Object to the form.

THE WITNESS: In my opinion, it means that when it's mechanically cut, there is pieces that will come off. And that is -- they've been doing that from the first use of the product from Prof. Ulmsten.

BY MR. HUTCHINSON:

Q. You mentioned a Velcro effect during the first day of your testimony. Do you remember that?

A. Yes, I do.

Q. Would you explain to the jury what you mean by Velcro effect?

A. The mesh, when it's cut, leaves the edges of the mesh exposed. And the mesh itself has an inherent strength, in terms of its stiffness in the width of the mesh, such that when it's pulled into the tissue, the edges of the mesh bind into the tissue and the mesh stays where placed. And it's like a -- it's been referred to by surgeons as a Velcro effect.

Q. Does that help with tissue ingrowth?

A. It helps with the immediate tissue fixation so that the woman immediately after surgery is continent.

Q. When you said earlier about the

inherent strength of the mesh, what do you mean by that?

A. The inherent strength of the mesh in terms of the mesh, if it's weaker, it will not exert the force in order to stay in the mesh, in the tissue, and can slip. And if it slips, then the woman is -- you know, before the ingrowth occurs, which occurs over time, then the placement that the mesh was done by the surgeon would move, and she most likely would become incontinent.

Q. Did plaintiffs' counsel ask you any other questions about this document?

MR. CARTMELL: I just object to the form.

THE WITNESS: I'm not sure.

BY MR. HUTCHINSON:

Q. Well, let's look at the first sentence in the second paragraph.

Do you remember if plaintiffs' counsel asked you any questions about that sentence in the second -- in the first sentence in the second paragraph?

MR. CARTMELL: Same objection.

THE WITNESS: No, there was no questions about that.

BY MR. HUTCHINSON:

Q. It states, "There is no reason to expect that the fraying of the mesh or the particles generated would create any safety risks." Do you see that?

A. Yes.

Q. Is that your opinion?

A. I would say that it's --

MR. CARTMELL: Object to the form. Sorry.

THE WITNESS: -- safe to agree with that.

BY MR. HUTCHINSON:

Q. Let's look at the third paragraph. It states, "Regarding efficacy, I am not aware of any studies comparing frayed and unfrayed tape. I am also not aware of any complaints that claim changes in efficacy when tape is frayed. No change in efficacy would be expected." Do you see that?

A. Yes.

Q. Did plaintiffs' counsel ask you any questions about that sentence?

MR. CARTMELL: Object to the form.

THE WITNESS: Absolutely not.

BY MR. HUTCHINSON:

Q. Let's look at the last page of this document.

And who is the author of this document?

A. It's Marty Weisberg, senior medical director.

Q. What does the last sentence of this document state?

Mr. Lawlor, can you highlight that for the jury, please.

A. "Since fraying does not affect the safety and efficacy of the...device, it has been determined not to pursue any corrective actions at this time."

Q. And does this document show that Ethicon's medical director, Marty Weisberg, evaluated the issues about fraying from a safety and efficacy point of view?

A. Yes, it does.

Q. Let's look at Exhibit 2154.

Do you have it in front of you?

A. I do.

Q. Do you remember being asked questions about this document?

A. Yes.

Q. Let's look at the second page. It's Bates number 323.

A. Yes.

Q. And is this a marketing communication about blue TVT mesh?

A. Yes. From Steve Bell.

Q. And does it address small pieces coming off the mesh?

A. Yes.

Q. All right.

Let's look at key point number 3. Mr. Lawlor, you can highlight that whole paragraph for us, please.

It states, "Reassure them that PROLENE is proven to be inert and there are hundreds of papers going back" to "25 years to reinforce this point. These particles will not cause any problem." Do you see that?

A. Yes.

Q. First, for the jury, what is exactly Prolene?

A. Prolene is a proprietary version of polypropylene, proprietary to Ethicon. It's mainly polypropylene with an additive which we call Prolene.

Q. And how long has Prolene been used in the human body?

A. I'm going to go back probably about 25 or plus years. It's been used primarily as a cardiovascular suture, and its unique properties of Prolene giving it some stretch characteristics of the fiber itself have been valued by the surgical community.

Q. Is Prolene a safe mesh to use in the human body?

A. Absolutely.

Q. I'm sorry?

A. Yes.

Q. Why do you say that?

A. It's been used for 25 years as a -- in the blood vessels in cardiovascular surgery. So it's proven, as well as all of the clinical trials done with TVT for the last 16 years.

Q. And did you author this document?

A. No, I did not.

Q. Who did?

A. It was a medical -- I mean, a marketing director, Steve Bell.

Q. Do you know what Steve Bell meant when he used the term "inert"?

MR. CARTMELL: Object to the form.

THE WITNESS: My assumption here is that in -- that the mesh is considered inert, that once the fibrotic response has cleared through the body, the mesh can reside in the body and it's considered inert.

BY MR. HUTCHINSON:

Q. What do you mean by fibrotic response?

A. As with any foreign body, the tissue reaction, there's minor tissue reaction called -- and then tissue response sometimes referred to as fibrotic action.

MR. HUTCHINSON: Just a second.

BY MR. HUTCHINSON:

Q. Mr. Smith, would you get Exhibit 367 for me, please.

- - -

(A discussion off the record occurred.)

- - -

BY MR. HUTCHINSON:

Q. 367?

A. Yes.

Q. Do you remember being asked questions

about that document?

A. Yes.

Q. And look with me on page 1. It states, "Hello David, Please see the attached letter from Mr....Dr. Eberhard." Do you see that?

A. Yes.

Q. Who is Dr. Eberhard?

A. I don't know.

Q. Do you know where he's from?

A. No. I assume he's from Germany.

Q. Why do you assume that?

A. Because he says, I hope you can understand a little bit of German.

Q. Let's look at page 2.

Is there --

Do you see the photograph at the bottom of the page?

A. Yes, I do.

Q. And do you recall being asked questions about that?

A. Yes, I do.

Q. And based on your knowledge, Mr. Smith, of the TVT products, is that photograph that Dr. Eberhard sent representative of mesh that comes out of a brand new box?

A. No, it's not.
Q. How do you know that?
A. It would -- looks like this mesh has been stretched is my opinion by -- or handling or physical abuse.
Q. And based on some of the documents we've seen, was this a demo unit?
A. There was another document associated, which was a translation of the German, and that translation of the German clearly stated that that -- that this was a demo unit which had been handled.
Q. And when looking at the photograph of this piece of mesh, does it appear to you that it's been stretched?
A. Absolutely.
Q. How can you tell?
MR. CARTMELL: Object to the form.
THE WITNESS: It has been necked down. There's two areas that seem to be the same width, and there's an area that particle loss has happened in, which has made it narrower.
BY MR. HUTCHINSON:
Q. Does it appear to be stretched beyond the elastic properties?

A. I would have to say in my opinion, yes.

Q. And based on your personal experience, have you ever seen a mesh that was actually used that's already been stretched beyond its elastic properties?

A. In clinical use?

Q. Yes.

A. Yes, I have.

Q. Tell us about that.

A. Prof. de Leval had placed a mesh in a patient who had -- I'm going to assume maybe, I think it was like four or five prior surgeries to cure her incontinence. And she was coming to Prof. de Leval. He placed a TVT-O. And in order to get her urethra in a position that he felt was appropriate, he pulled extremely hard and the mesh basically was roped and looked similar to this, if not less than this.

Q. And what was the clinical result?

MR. CARTMELL: Object to the form.

THE WITNESS: I -- she was dry immediately after the surgery. And I personally followed up the following year and -- with Dr. de Leval and asked if she was still incontinent, and he

said she was.
BY MR. HUTCHINSON:
Q. You meant she was still incontinent?
A. Incontinent.
MR. CARTMELL: Object to the form.
THE WITNESS: Sorry.
MR. HUTCHINSON: That's okay.
BY MR. HUTCHINSON:
Q. Does this photograph at the bottom of this exhibit appear to be an extreme case to you?
MR. CARTMELL: Object to the form.
THE WITNESS: I would say yes.
BY MR. HUTCHINSON:
Q. But even in this extreme case, would it still be acceptable to put this piece of mesh in the human body, provided, of course, it was appropriately sterilized?
MR. CARTMELL: Object to form.
THE WITNESS: I would say that it would function, yes.
BY MR. HUTCHINSON:
Q. Do you remember, Mr. Smith, about testifying about how the mesh is constructed in terms of course and wales?
A. Yes.

Q. What do you mean by that?

A. Courses and wales define the porosity of our mesh. And the -- this particular mesh, although it may lose particles on either side when it's mechanically cut, as long as it has a sufficient number of courses and wales, which is defined by the width of the mesh of 1.1 centimeters wide, the mesh may fray or look like that picture, but it will not rip or tear in terms of completely fall apart and separate.

Q. Does it make the mesh stay intact more or less from a clinical perspective?

A. It makes it clinically functional.

MR. CARTMELL: Object to the form. You're asking him all about clinical stuff. And we spent two days with him telling us that he can't answer clinical questions. I just want the record to be clear.

BY MR. HUTCHINSON:

Q. Mr. Smith, based on your personal knowledge, does mesh fraying have any adverse effect on patient safety?

A. I have not heard of any.

Q. Based on your personal knowledge, does mesh fraying have any adverse effect on

efficacy?

A. I have not heard of any.

Q. Let's talk about the same questions as it relates to particle loss.

Based on your personal knowledge, does particle loss have an adverse effect on patient safety?

MR. CARTMELL: Object to the form.

THE WITNESS: I have never seen any information that said -- would say that it did.

BY MR. HUTCHINSON:

Q. Based on your personal knowledge, does particle loss have any adverse effect on whether or not the product works?

MR. CARTMELL: Object to the form.

THE WITNESS: Absolutely not.

BY MR. HUTCHINSON:

Q. Let's look at Exhibit 2157.

MR. HUTCHINSON: Dan, we got to take a quick break, because we're running out of tape.

THE VIDEOGRAPHER: The time is now 4:47. This is the end of Disk Number 5. We are going off the record.

- - -

(A recess was taken from 4:47 p.m. to

4:54 p.m.)

- - -

THE VIDEOGRAPHER: The time is now 4:54. This is the beginning of Disk Number 6. We are back on the record.

BY MR. HUTCHINSON:

Q. Mr. Smith, we are now back on the record after we had to take a quick break to change tapes.

Would you look at Exhibit 2143 with me, please?

A. I have it.

Q. Do you remember being asked questions about this document?

A. Yes, I do.

Q. And would you identify this document for the jury, please?

A. It's a risk document, sometimes referred to as a DDSA or an FMEA.

Q. And what is the purpose of a risk document such as this?

A. It identifies the known and/or possible known conditions of harm or risk and identifies the severity, the probability, of those associated and identified risks. And you collect

them in -- on here, and it becomes a living document that gets revised and looked at as throughout the life of the product.

Q. And do you recall being asked questions about whether or not the actual mesh of the TVT product was associated with this risk report?

A. Yes.

Q. And is this risk assessment associated with the actual mesh of the TVT product?

A. It is for the complete product, which includes the mesh.

Q. And how can you tell?

A. Its various references within the document that look at bleeding or damage to the urethra or placement of the device itself. It's typically done on finished devices, so this is a finished device.

Q. Let's look at page 1 a little bit more closely. And, Mr. Lawlor, if you'll help us with the highlighting.

When was this document originally prepared?

A. It looks like in 1998.

Q. Would that be September?

A. September of '98.
Q. Would that be shortly before the time frame that TVT was launched in the United States?
A. Yes.
Q. And what is the revision date of this?
A. 2000, in July 2000.
Q. And how many revisions does it have?
A. I believe it has eight revisions. This is the eighth revision.
Q. And let's look at page 2.
On the left-hand side, there's some language there. Do you see that?
A. Yes.
Q. What does that tell us?
A. It identifies the numerous revisions that were done to this document over time.
Q. And, Mr. Smith, do you remember being asked questions about whether this document in total addresses extrusion, erosion or exposure?
A. Yes, I do.
Q. Are those exact words in this document?
A. No. If I recall, my testimony was that they were referring in this document to tissue

damage. Those exact words, however, are contained in the IFUs of the -- for TVT.

MR. CARTMELL: Object and move to strike the testimony that was nonresponsive.

BY MR. HUTCHINSON:

Q. Let's be clear, Mr. Smith.

When we talk about tissue damage, does this document use the word "tissue damage"?

A. I believe it does.

Q. Turn with me, please, to 518.

A. Yes.

Q. Are you there?

A. Yes.

Q. All right. I'm waiting on the IT.

Tissue damage, fourth box down.

Do you recall being asked questions about that?

A. Yes, I do.

Q. And how does tissue damage relate to extrusion, erosion or exposure?

A. It could be similar in terms of, you know, nature in terms of the exposure. This document here just speaks of it as tissue damage in a general sense.

Q. So my question, Mr. Smith, were the

potential harms of extrusion, erosion or exposure excluded from this risk analysis?

A. In my opinion, I don't believe they were.

Q. And are erosion and extrusion listed in the IFU?

A. Yes, they are.

Q. Let's look at Exhibit 2147, please.

Do you recall being asked questions about this document? Oh, I'm sorry. It should be pretty close to the one --

A. Yeah.

Q. There you go.

A. Trying to keep them in order here. Got it.

Q. You have Exhibit 2147 in front of you?

A. Yes.

Q. And do you recall being asked questions about this document?

A. Yes, I do.

Q. And for the jury's benefit, would you identify this document, please?

A. This is a biannual DDSA review of the risk assessment that was just looked at called

TVT-2. This was done by Sue Meltzer, external quality, to review the complaint data and then update if necessary the risk assessment.

MR. CARTMELL: What's the exhibit number, I'm sorry?

MR. HUTCHINSON: 2147.

BY MR. HUTCHINSON:

Q. Is this the way that Ethicon is proactive in evaluating the safety of its products?

A. Absolutely.

Q. Let's look at the third paragraph.

A. Uh-huh.

Q. It says, "Evaluate eleven (11) potential new hazards for inclusion in the DDSA." Do you see that?

A. Yes.

Q. And it lists several bullet points there below. Do you see that?

A. Yes.

Q. Are these new hazards that Ethicon didn't know anything about?

A. No. They were listed in the IFU in the same time frame.

Q. Let's look at Exhibit 2160.

A. I have 2159.

Q. It looks --

A. And I have 2161.

Q. It looks like this. Look on your far left side. Far left. Is that it? 2160?

A. I have 59 and I have 61.

- - -

(A discussion off the record occurred.)

- - -

MR. HUTCHINSON: We'll go off the record for just a minute while we find it.

THE VIDEOGRAPHER: The time is now 5:02. We're going off the record.

- - -

(A recess was taken from 5:02 p.m. to 5:03 p.m.)

- - -

THE VIDEOGRAPHER: The time is now 5:03. We're back on the record.

BY MR. HUTCHINSON:

Q. Mr. Smith, we're back on the record, and you have in front of you Exhibit 2160. Correct?

A. Correct.

Q. Do you remember being asked questions about this document?

A. I do.

Q. And would you identify this document for the jury, please?

A. It is a risk assessment document, FMEA.

Q. And what is the purpose of this document?

A. This was done for the mesh, the laser cut mesh project.

Q. Why?

A. To assess any potential risks that the change of mechanically cut to laser cut might have. So it was a risk document done specifically for the change from mechanical cut to laser cut mesh.

Q. And let's look at page 3 of 7.

Could you blow that chart up for the jury, please.

Mr. Smith, why don't you describe for the jury what this chart consists of?

A. It can -- it looks at the component's function, and we also, for any given activity going to -- from left to right, it would look at the potential hazard, the harm, as well as the occurrence and a control method. Based on the

procedure that's used with this document, you would rank and rate the individual concerns of the components, and you would get in a -- what was called an RPN number at the end, which is a risk number, risk potential number.

Q. And if you can -- Mr. Lawlor, if you zoom in on line 8, please.

Mr. Smith, do you remember being asked questions about this particular line item?

A. Yes, I do.

Q. And under "Potential Failure Mode," what does it state?

A. "Potential Failure Mode," it says, "Mesh slips in tissue."

Q. And then if we go over, what else do you see?

A. Potential "loss of device functionality. Mesh...provides partial repair."

Under the "Harm," it would be "Erosion."

The "Potential Cause" would be the mesh -- "Reduction in mesh width due to roping."

And then the "Control," which would be "Ultrasonic Mesh study for pull-out," which was used and there's an accession number there, which

means it went through our corporate characterization group.

And so basically -- and then it's rated and ranked for the potential causes and harms. But, in essence, the study would say that the use of ultrasonic cut mesh, similar to laser cut mesh, would mitigate some of the risk.

MR. CARTMELL: Object and move to strike the part that's nonresponsive.

BY MR. HUTCHINSON:

Q. Mr. Smith, I remember you being asked questions about the specific box that states erosion here.

A. Yes.

Q. Do you remember that question?

A. Yes, I do.

Q. Would you need to evaluate that specific box against some of the other boxes in this document?

A. Absolutely.

Q. Like what?

A. You would need to look across all the lines, and that particular box, number 8, was regarding to the assembly. I believe there was other boxes, such as I think 18, "Reduction

in...pore size," which would link to the mesh changing shape.

Q. And let's actually look on page 4. I think you're already there with me.

Do you recall being asked questions about line 17 and line 19?

A. I do.

Q. And if we look there under "Potential Failure Mode," both of them state, "Tissue in-growth does not occur." Do you see that?

A. That's correct.

Q. What else does this chart tell us about that potential harm?

A. It tells us that the occurrence is extremely low, it was rated a 1. And it tells us that it's -- the mitigation would be using the existing mesh that's on TVT-Base devices, Classic and TVT-O, which is the gold standard. So what it's saying is that there's very little chance of that happening because of the mesh being used.

MR. CARTMELL: You trailed off, I'm sorry. Little chance of it happening because of?

THE WITNESS: Because of the mitigation column, "Control Method," of the use of TVT mesh.

BY MR. HUTCHINSON:

Q. Mr. Smith, turn to some of the exhibits that you were asked about today.

If you'll look at Exhibit 2161 for me, please.

And specifically I want you to turn your attention --

Or actually, before we do that, do you recall being asked questions about this document?

A. Yes, I do.

Q. And would you identify to the jury, please, what this document is?

A. It's a risk management report prepared by the risk group or -- this is part of the Quality group.

Q. And if you'll turn, please, with me to page 228.

Do you remember being asked questions about this particular page?

A. Yes, I do.

Q. And who makes the final decision on which harms are included in this harms/hazards summary table?

A. The responsibility of this document

is the medical director mainly, as well as quality.

Q. And do you remember being asked questions during your deposition about what input that you gave?

A. Yes, I do.

Q. And if I recall, you testified that you gave technical input if needed?

A. That's correct.

MR. CARTMELL: Object to the -- and misstates -- objection to the form.

THE WITNESS: That's correct.

BY MR. HUTCHINSON:

Q. What do you mean by giving technical input if needed?

MR. CARTMELL: Same objection.

THE WITNESS: Depending on the questions and the discussion at the time of the group, that's going on in the group, I would make sure that the -- the discussion was relevant to the design of the device, not relevant to whether or not, you know, I pick the category or whether or not I assigned a severity or harm as in -- that would be the medical director's position.

BY MR. HUTCHINSON:

Q. And if we look on this page, I see

the second column, it states, "Severity of Harm," and there's different numbers given down for harms; is that correct?

A. That's correct.

Q. Who makes the final decision about which numbers these harms get?

A. Medical director.

Q. And if we look on there on the fourth column, it states, "Estimated Frequency of Harm." Do you see that?

A. Yes.

Q. Who makes the final decision about which numbers are inputted there?

MR. CARTMELL: Objection, asked and answered.

THE WITNESS: It would be medical director and quality.

BY MR. HUTCHINSON:

Q. And where --

And who was the medical director?

A. David Robinson.

Q. Do you know where Dr. Robinson got that information?

MR. CARTMELL: Objection, calls for speculation.

THE WITNESS: No, I don't.

BY MR. HUTCHINSON:

Q. Would Dr. Robinson be the better person to answer these questions?

A. Yes.

Q. About the -- excuse me.

About this document?

A. Yes.

Q. And if we look on the harms/hazards summary table, do you see those harms that are included on the left side?

A. Yes.

Q. And are these risks included within the IFU?

MR. CARTMELL: Object to the form.

THE WITNESS: Yes.

BY MR. HUTCHINSON:

Q. Mr. Smith, let's look at Exhibit 2126, please.

THE COURT REPORTER: There is no 2126.

THE WITNESS: 2138 is the first one.

MR. HUTCHINSON: Well, I have what Mr. Cartmell gave me as Exhibit 2126.

MR. CARTMELL: Is this the timeline?

MR. HUTCHINSON: This is the timeline. That's what I have it as.

MR. CARTMELL: 2166.

MR. HUTCHINSON: All right. My bad.

THE WITNESS: There is a 2166.

BY MR. HUTCHINSON:

Q. Why don't you get 2166 out there.

A. Wrong pile.

I have it.

Q. Have you seen this document before today?

A. No.

Q. Let's look at the second page where you have the chart.

What is the mesh used in TVT, Mr. Smith?

MR. CARTMELL: Object to the form.

THE WITNESS: It's -- TVT has a 6 mil polypropylene fibers which construct the TVT mesh.

BY MR. HUTCHINSON:

Q. Is this what we've seen or what was defined as "old mesh" in some of the documents we've seen?

A. Yes. Or old mesh or TVT.

Q. And was this the same mesh that Dr.

Ulmsten started with in the very beginning when he developed TVT?

MR. CARTMELL: Object to the form.

THE WITNESS: Yes.

BY MR. HUTCHINSON:

Q. Is the mesh any different than the mesh Dr. Ulmsten started with to your -- in your -- to your knowledge?

MR. CARTMELL: Object to the form.

THE WITNESS: Not in design or construction. However, it -- he started, it was a clear mesh. We now have clear and blue mesh.

BY MR. HUTCHINSON:

Q. And the mesh that Dr. Ulmsten used, does it have any clinical data supporting it?

MR. CARTMELL: Object to the form.

THE WITNESS: Yes.

BY MR. HUTCHINSON:

Q. What?

MR. CARTMELL: Object to the form.

THE WITNESS: It was clinical studies that were attached to the 510(k) which was submitted.

MR. CARTMELL: Do you want to restate that? Because I was in the middle of his answer.

MR. HUTCHINSON: Okay. My question was, what, and you objected to the form on that.

MR. CARTMELL: What was it in it? Yeah, I'm objecting to all of this, because he has no foundation. He has no idea. He wasn't even at the company, and he told me that, at the time.

MR. HUTCHINSON: All right. You can cease from making speaking objections.

BY MR. HUTCHINSON:

Q. Mr. Smith, to your knowledge, did Dr. Ulmsten have any clinical data to support the TVT mesh?

MR. CARTMELL: Object to the form.

THE WITNESS: The files that I reviewed for this deposition were from the Medscand files as well as the 510(k)s, which were submitted by Ethicon which included Dr. Ulmsten's clinical trials.

BY MR. HUTCHINSON:

Q. Let's look at exhibit --

A. If I could be correct. They include his clinical trial outcomes, to my knowledge.

Q. Thank you.

MR. CARTMELL: I object and ask that the entire line of testimony be stricken based on

his testimony already to me that he never saw a clinical trial, all he saw was a few pieces of paper that referred to a clinical trial. He never saw a protocol, he never saw data, he never saw any of that.

MR. HUTCHINSON: Counsel, in all due respect, I did not make any speaking objections when you were asking questions. And I'll ask that you refrain.

BY MR. HUTCHINSON:

Q. Mr. Smith, would you get Exhibit 2169 out in front of you, please.

Do you remember being asked questions about this document?

A. I do.

Q. And what is this document?

A. It was a page from another PowerPoint presentation, if I recall. And it lists some meshes that are sold by Ethicon as well as some meshes that aren't. And it lists their weights.

Q. And which meshes are sold by Ethicon?

A. Gynemesh, Gynemesh PS or Prolene, TVT, Vypro and Mersilene.

Q. And which are not sold by Ethicon?

A. Marlex, IVS and Surgipro, off of this

chart.

Q. And do you recall being asked questions about which TVT or which actual mesh, rather, has a great -- the greater weight numerically?

A. Yes.

Q. And which mesh is that?

A. It's the TVT, which has a 94.

Q. And what is significant about that, if anything?

MR. CARTMELL: Object to the form.

THE WITNESS: It was stated to be more weight than the other meshes that Gynecare sells. In my opinion, the significance of that is limited prior -- because TVT is such a small piece of mesh relative to pelvic floor meshes, which the other meshes listed here are pelvic floor meshes.

BY MR. HUTCHINSON:

Q. That's the distinction then that I want to ask you about.

Which of these meshes are actual pelvic floor meshes?

A. Gynemesh or Gynemesh PS.

Q. If you could slow down just a minute, because I want to be precise on this.

Which of these are pelvic floor meshes?

A. Gynemesh PS, for instance.

Q. Okay.

A. It's -- I did not create this chart, so Gynemesh is generic, Prolene is generic. The only one that's on this list that's used in SUI is TVT.

Q. And other than TVT, would it be appropriate for using any of these other meshes in SUI surgery?

A. In my opinion, no.

Q. Why not?

MR. CARTMELL: Objection.

THE WITNESS: TVT, obviously the only mesh that's been used in SUI surgery from a Gynecare perspective for the 15 or 16 years. The Prolene -- the Gynemesh PS mesh, PS mesh listed on this page here, is a very light mesh, has very limited stretch characteristics. TVT has a defined elongation property for it.

BY MR. HUTCHINSON:

Q. Mr. Smith, based on your experience, what do you mean by Gynemesh PS having a limited stretch?

A. The weave of Gynemesh PS is very different from the TVT construction, such that it does not have elongation properties anywhere near the TVT mesh, of which Prof. Ulmsten specifically wanted TVT to have the unique stretch properties that was created back in 1997.

Q. How is the weave of TVT mesh different than Gynemesh PS?

A. It's not similar at all.

Q. How are they different?

A. It would be almost difficult to even describe without looking at them. It's not -- they're not even close to the same.

Q. Would it be appropriate in your opinion, based on your experience, to use Gynemesh PS in any type of SUI product?

A. In my opinion, no. And there is no SUI products on the market that use any mesh similar to that of Gynemesh PS in SUI surgery.

MR. CARTMELL: Object. I apologize. Object and move to strike after the answer.

BY MR. HUTCHINSON:

Q. What about Ultrapro?

MR. CARTMELL: Same objection. Or objection to the form.

THE WITNESS: Ultrapro mesh is also a POP mesh, or a pelvic floor repair mesh.

BY MR. HUTCHINSON:

Q. Okay.

A. Its characteristics in my opinion also would not be suitable, and primarily because of the very stretchable characteristics that that particular mesh has relative to TVT, meaning that it has greater elongation properties and also a property sometimes referred to as roping. So as it is stretched, it narrows and could cause roping or retention.

Q. Mr. Smith, let me clear the record. Would Ultrapro -- actually, let me back up.

What is Ultrapro?

A. Ultrapro is a mesh, a partially absorbable mesh used in pelvic floor surgery. It has yet even a different construction and weave.

Q. Based on your experience, would Ultrapro be suitable for an SUI product?

A. No, it would not.

Q. Why not?

A. As I was indicating, the elongation properties of Ultrapro would cause it to neck and narrow and stretch greatly, even during implantation

or after implantation.

Q. What do you mean by "elongation properties"?

A. Much like an elastic band. It behaves more like an elastic band than TVT does. Where TVT has resistance, it has some elastic properties if stretched, whereas Ultrapro would stretch many times or multiple time more. It's just hard to define, but...

Q. If you will look, please, with me at Exhibit 2172.

Do you have that in front of you?

A. Yes, I do.

Q. Do you remember being asked questions about this document?

A. Yes, I do.

Q. Does this apply to hernia repair or POP surgery?

A. Yes.

Q. Does it apply to SUI surgery?

A. No.

Q. Did you author this document?

A. No.

Q. Do you hold yourself out to be an expert in histology?

A. No.

Q. For the benefit of the jury, what is histology?

A. It's the evaluations of tissue ingrowth or tissue, cell and tissue in general.

Q. If we look at this document that you have in front of you, 2172, do you remember being asked questions about the benefits of large pores?

A. Yes.

Q. And do you remember being asked questions about the conclusions of this evaluation?

A. I believe so, yes.

Q. And were the conclusions for pelvic floor repair products instead of stress urinary incontinence products?

MR. CARTMELL: Object to the form.

THE WITNESS: It's what the intent of this document was.

BY MR. HUTCHINSON:

Q. Mr. Smith, would you turn with me, please, to Exhibit 2168.

Before we go there, though, I want to ask you a question.

Do you remember being asked about -- questions by plaintiffs' counsel about heavyweight

mesh versus lightweight mesh?

A. Yes.

Q. And what did you mean when you testified that you cannot agree that it is a heavyweight mesh? What did you mean by that?

A. In my opinion, TVT has -- isn't defined as a heavyweight mesh, so there's characterization and people define meshes in heavyweights and lightweights. In my experience, it's been called TVT. It has a 6 mil fiber and it's not necessarily, in my mind -- it may be considered a heavyweight mesh. I don't consider it a heavyweight mesh. That's all.

Q. Let's look at Exhibit 2168, please.

Do you have that in front of you?

A. Yes, I do.

Q. And do you recall being asked questions about pore sizes?

A. I do.

Q. Let's look at --

Actually, do you recall being asked questions about large pores and small pores?

A. Yes, I do.

Q. Let's look at page 16 for a minute.

Are you there?

A. Yes.
Q. It states at the top, "Pores must be greater than 75 microns." Did I read that correctly?
A. Yes.
Q. What does that mean?
A. The Amid study, which has held up pretty much in respect to pore size, it was defined that anything greater than 75 microns would be considered a large macroporous mesh. 75 microns is three-thousandths of an inch, which is roughly the size of your hair. The pores in TVT mesh are roughly a millimeter, which is a thousand microns. So we're talking about 75 microns versus a thousand microns, which is what a TVT mesh is. So we're obviously a larger pore size than what's considered a macroporous mesh.
MR. CARTMELL: Object to the form -- or excuse me. Object to the testimony as nonresponsive. Move to strike.
BY MR. HUTCHINSON:
Q. Down at the bottom, the first paragraph, it says, "Searchers have shown through histological studies that a good incorporation requires pores greater than 75 microns." Did I read

that correctly?

A. Yes, I believe so.

Q. And, Mr. Smith, are the pores in the TVT mesh greater than 75 microns?

A. Yes. They are -- pores in TVT mesh are approximately 1,000 microns.

Q. Let's look at page 24.

Do you recall being asked questions -- actually, strike that.

Are you with me on page 24?

A. Yes.

Q. It states at the bottom -- I mean, I'm sorry, at the top, "The chemical nature of the material. Select an inert material: No scientific evidence suggesting to use something else than POLYPROPYLENE." Do you see that?

A. Yes.

Q. What does that mean?

A. It's written by the medical directors here, this document. It's saying that after the initial inflammatory response, the material is inert.

Q. And it states down at the bottom, a paragraph that I don't believe you were asked about, where it says "Select an inert material." Do you

see that?

MR. CARTMELL: Object to the form.

THE WITNESS: Yes.

BY MR. HUTCHINSON:

Q. Were you asked about this paragraph?

A. I don't believe so.

Q. What does it state?

A. "Polypropylene has been used for years in surgery and its perfect tolerance in the human body has been established. It is the number one suture used in cardiovascular surgery. It is by far the most widely used mesh...both" in "hernia repair" as well to "cure...SUI. To date, there is currently no scientific evidence suggesting" any other "material would have a better effect in minimizing the inflammatory reaction of the host tissues."

Q. All right.

And if you'll turn with me to page 40, please. It's the very last page. You can blow up that paragraph at the bottom that starts, "As far as slings are concerned."

Mr. Smith, this is the last page of this document. Correct?

A. Yes.

Q. And it states "Conclusions" at the top?

A. Yes.

Q. Did plaintiffs' counsel ask you any questions about this particular page of the document?

MR. CARTMELL: Object to the form.

THE WITNESS: Not at all. Not at all.

BY MR. HUTCHINSON:

Q. Down there at the bottom it has two bullet points. Do you see those?

A. Yes.

Q. What does the first bullet point state?

A. "As far as slings are concerned, the huge and long term experience with the Gynecare TVT is the best guarantee for the pelvic floor surgeon that he will very seldomly have to face vaginal complications."

Q. Okay.

Let me ask you to switch gears for a minute and ask you a few questions about the Scion project and the Matrix project. Okay?

A. Okay.

Q. Let's talk about the Scion project first.

What was the purpose of that project?

A. The Scion project was initiated as a next-generation product potential after TVT SECUR. It was initially stated to try to improve the product on some of the things that we had seen with TVT SECUR post-launch, such as having a longer mesh, single placement device, rather than both retropubic and obturator, absorbable ends and the like.

Q. Did you get any voice of the customer feedback?

A. Since the project went on for numerous years, we had a lot of VOC or voice of customer. Almost all surgeons who we showed it to were very pleased with the device and anticipated us in launching the device.

Q. Was it your job as an engineer within the R&D department to bring new ideas to the table?

A. Yes.

Q. And is that what you were doing with the Scion project?

A. Yes.

Q. Did a finished product ever come out of this project?

A. No, it did not.
Q. Why not?
A. The company --
MR. CARTMELL: Objection, asked and answered.
THE WITNESS: The company determined that it was a business decision to no longer pursue that as a product.
BY MR. HUTCHINSON:
Q. Let's talk about the Matrix project for a minute.
What was the purpose of the Matrix project?
MR. CARTMELL: Asked and answered.
THE WITNESS: Matrix was a research project that myself and another individual from Germany undertook to evaluate different materials. In this case, it was a material that -- not a mesh, but we were -- the material would have a minimal amount of polypropylene in it. The goal was to understand how low or how little polypropylene we could actually put in a material and have it functionally -- and function. And we looked at whether or not it would have application both in SUI or pelvic organ prolapse.

BY MR. HUTCHINSON:

Q. What was the result?

MR. CARTMELL: Objection, asked and answered.

THE WITNESS: We studied it for numerous years, numerous animal studies, and there was no conclusive result that came out of it to -- that that material would serve as a good material for replacements at this point.

BY MR. HUTCHINSON:

Q. Is this an example of you as a fellow engineer trying to bring new ideas to the table?

A. It's an example of, not only myself, but Ethicon looking for better materials or better solutions.

MR. CARTMELL: Move to strike as nonresponsive.

BY MR. HUTCHINSON:

Q. Let's talk about TVT-O PA.

What was that?

A. TVT-O PA was a project. It came after TVT -- or after, excuse me, Scion. Scion originally started as a polypropylene mesh, went to -- eventually went to a PA mesh. When we created the mesh, which could -- a partially absorbable

mesh, it was then determined that we wanted to put it onto a different product with TVT-O and test it clinically. And so we created a project called TVT-O PA.

Q. What was the ultimate result of the TVT-O PA?

MR. CARTMELL: Objection, asked and answered.

THE WITNESS: The TVT-O PA product was created, clinical samples were developed. And prior to the clinical actually being executed, it was determined that the product did not function effectively in some human cadaver studies that were done and that it had too much elongation or stretch. So it was -- the project was canceled.

BY MR. HUTCHINSON:

Q. Let me ask you this.

Out of all the projects that we've talked about, what material have you found that would have the characteristics needed to replace Prolene as the mesh used in the gold standard TVT?

MR. CARTMELL: Objection, asked and answered.

THE WITNESS: I have not found anything that's close. We -- the PA mesh was

attempted to be designed to be as close to or identical to the TVT mesh having an absorbable component to it. But as we said, it was not successful.

BY MR. HUTCHINSON:

Q. Why has Ethicon continued to use Prolene in its mesh for TVT products?

A. Prolene, I would say, as a material is the most proven mesh. It's the gold -- it's considered the gold standard.

Q. I want to clear something up.

If I recall, when you were deposed, you testified that you've never done a study -- there's never been a study done by the company to test a PA mesh for SUI.

MR. CARTMELL: Objection, move to strike the statement of counsel.

BY MR. HUTCHINSON:

Q. What do you mean by that?

MR. CARTMELL: Same objection.

THE WITNESS: There was a study planned to be done, but it was not carried out due to experiencing the product before use that it would not behave properly due to its stretch characteristics prior to being placed in the body.

BY MR. HUTCHINSON:

Q. And what project are we talking about?

A. That was the TVT-O PA project.

Q. Mr. Smith, do you or Ethicon -- or strike that.

Do you know of a mesh that is safer and more effective than the Prolene mesh already used in the TVT products?

MR. CARTMELL: Object to the form.

THE WITNESS: No.

BY MR. HUTCHINSON:

Q. Do you remember being asked questions about information that would be reasonable for a woman to know about having a TVT device implanted in their body?

A. Yes.

Q. Based on your experience, Mr. Smith, do all surgeries carry risks?

A. Absolutely.

Q. And whose responsibility is it to warn the patients of those known risks?

MR. CARTMELL: Object to the form.

THE WITNESS: It's the surgeon's responsibility.

BY MR. HUTCHINSON:

Q. And do you remember plaintiffs' counsel asking you questions about what you'd want your wife or daughter to know about the risks?

A. That's correct.

Q. And, Mr. Smith, if your wife or daughter suffered from stress urinary incontinence and wanted to improve the quality of their life, what would you recommend?

MR. CARTMELL: Object to the form.

THE WITNESS: I would recommend one of the TVT family of products, either TVT SECUR, TVT-O, TVT, but the surgeon would have to make that determination as to which one of those products would be best.

MR. HUTCHINSON: Thank you. No further questions.

We'll go off the record.

MR. CARTMELL: Go off the record for just a second.

THE VIDEOGRAPHER: The time is now 5:39. We are going off the record.

- - -

(A recess was taken from 5:39 p.m. to 6:03 p.m.)

- - -

THE VIDEOGRAPHER: The time is now 6:03. We are back on the record. This is the beginning of Disk Number 7.

MR. HUTCHINSON: Tom, real quick before we go into your line of questioning, it's 6:00. How long do you anticipate? Because we do have some flights to catch, but I do want you to have the opportunity to do a redirect or recross, rather, limited to our redirect.

Can you give me an approximation of how long? Because, in all honesty, the witness's back is hurting and it's now 6:00.

MR. CARTMELL: I don't know. You just did a two hour approximate direct. You brought up a lot of stuff, a lot of new issues, frankly, and I feel like we need to respond to those.

MR. HUTCHINSON: All right. Go on.

I can't agree to give you a whole hour, in the interest of time.

MR. CARTMELL: Pardon me?

MR. HUTCHINSON: I can't agree to give you a whole hour, in the interest of time.

MR. GOZA: Let's just start and see.

MR. HUTCHINSON: Just go on.

- - -

EXAMINATION

- - -

BY MR. CARTMELL:

Q. Mr. Smith, you just testified, I believe, that your company does training for physicians. Correct?

A. In the form of an IFU.

Q. Right.

And what you mean by that is you specifically train physicians by using or through the IFU. Correct?

A. Yes.

Q. And so it's clear that if the IFU is not correct, then the training will be defective. Correct?

A. Hypothetically.

Q. And it's also true that if the IFU is not correct, then the product of that, the training, and the IFU and the product as a whole will be defective. Correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: I can't answer that as a yes or no the way it's stated.

BY MR. CARTMELL:

Q. If you assume that the IFU is incorrect, then we know that the IFU is a part of the product. Correct?

A. Correct.

Q. If the IFU is incorrect, then the product will be defective. Correct?

A. The IFU would need to be changed.

Q. Well, and the product would be defective if it was incorrect?

A. The product would need to be changed -- I mean, the IFU would need to be changed if you're speaking of the IFU. The product may have nothing wrong with it.

Q. The IFU is part of the product. Right? We've already established that. Correct?

A. So the product would need to be altered.

Q. Right.

Because there may be a defect as a result of the incorrect IFU. Right?

MR. HUTCHINSON: Object to form.

THE WITNESS: Hypothetically speaking, yes.

BY MR. CARTMELL:

Q. Now, you just testified, I think,

that you believe the TVT products are safe?

A. I do.

Q. Now, you, as we know, spent years and years of your life, approximately nine or ten years, in the development and the design and in handling the technical aspects of those products. Correct?

A. Fair enough to say.

Q. I take it -- and I think you said, you testified that you're very proud of those products. Correct?

A. I am.

Q. I take it that if in fact those products were found to be unsafe or defective or to cause risks that outweighed the benefits, you'd feel some responsibility for those -- for that; is that right?

A. Hypothetically, if that was the case, they would need to be changed.

Q. Right.

And you would feel some responsibility for that, because you personally were involved in designing and developing those products. Right?

MR. HUTCHINSON: Object to form.

THE WITNESS: Yes.

BY MR. CARTMELL:

Q. You talked about recommending the use of the TVT SECUR, but the TVT SECUR is no longer being sold by your company. That's right?

A. That's right.

Q. And the reason for that is because the FDA said that your company needed to do further clinical studies related to that to determine whether or not the product was safe or effective. Correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: They -- the FDA indicated that additional 522s would need to be done for numerous mesh products.

BY MR. CARTMELL:

Q. The FDA --

A. That was one of them.

Q. I'm sorry.

A. And that was one of them, yeah.

Q. The FDA said, for the TVT SECUR product that you designed and developed, longer term clinical studies about safety of the product needed to be performed by the company. Correct?

A. That's correct.

Q. And your company chose as a business

decision, I think is what we've been told, not to pursue those studies. Right?

A. That was their choice, yes.

Q. I want to talk to you about Exhibit 2160, if you'll refer back to that.

Mr. Lawlor.

2160, as you recall, is the risk assessment related to the laser cut mesh that you were just asked again about?

A. Correct.

Q. And we went through this, and you testified that failure modes included in this were that the laser cut mesh could decrease in pore size, not integrate into the tissue and cause erosions. Correct?

A. That was your words that you were reading, yes.

Q. That's what it says on the document. Correct?

A. Right.

Q. And it also talks about how the mesh can slip and it can cause erosions. Right?

MR. HUTCHINSON: Object to form.

THE WITNESS: That was indicated by the people who put this together, yes.

BY MR. CARTMELL:

Q. And this involved engineers from your company, a medical director from your company and a team of people. Correct?

A. Yes. I was not part of that, but yes.

Q. And you mentioned that, I think what you said was, we did some controls that made this unlikely, or I think you said "rare" was your word. Right?

A. I think -- I believe I indicated that the control method was to use the TVT mesh.

Q. Well, yeah. What you're -- I just want to be clear.

What you're telling the jury is the control method was, we're using a TVT-O mesh or a TVT mesh that has been on the market for several years. That's what you're saying. Right?

A. Right. Relative to your statement of that pore size being smaller than the TVT mesh, that that would be rare, because the mesh pore size would stay above the 75 microns.

Q. Well, but what you're saying is the control there is because it's been on the market for several years, and because we say there hasn't been

any problems with it that we've seen in our reporting of complaints, that's one control?

A. That's right.

MR. HUTCHINSON: Object to form.

BY MR. CARTMELL:

Q. And the other thing that's listed as a control is a study. Right?

A. I believe so, yes.

Q. And the study that is listed we've talked about in this deposition, haven't we?

A. If you could give me reference, are we speaking of the same study?

Q. Well, that study that's listed there, if you go to -- let's go to 18 that we were talking about, or what you talked about a minute ago with defense counsel. Actually, I think it's 19, I apologize.

When you go to the control method related to the reduction in pore size causing erosion, it states, "Ultrasonic Mesh study for tissue in-growth, PSE accession number 02-0579"?

A. That's correct.

Q. That's the rabbit study that we talked about, isn't it?

A. I believe it is.

Q. That's the study that is ten rabbits for 14 days?

A. As an endpoint.

Q. Right.

So what happened in that study we've discussed is five of the rabbits got a little piece of mesh that was the TVT laser cut mesh, I take it?

A. I could look at the study. It was not my study, but --

Q. Well, the truth is that it wasn't the laser cut mesh, because that study, as we discussed, talked in -- or took place in 2003. Right?

A. That's correct.

Q. So this is a laser cut mesh FMEA, or risk analysis, that is referring to the control of the problem being erosion from small pores, being a rabbit study that was done in 2003 and not with laser cut mesh. Correct?

MR. HUTCHINSON: Object to form.

BY MR. CARTMELL:

Q. Is that true?

A. It was -- used ultrasonically-cut mesh.

Q. Right.

It did not use the laser cut mesh

that is being analyzed in this risk analysis. Correct?

A. There's reasons for that, but yes.

Q. Well, the reason for that and the reason laser cut mesh wasn't used in the rabbit study was because it wasn't even in existence at that time. Isn't that true?

A. It was being put in as part of this program.

Q. Right.

So it didn't exist at that time.

And so in the rabbit study, they did not put laser cut mesh that was sold to women in the rabbits' pelvis. Correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: No. They put ultrasonically-cut mesh, which effectively does the same job by welding the ends together, whether it's welded by heat, a light heat or sound heat.

BY MR. CARTMELL:

Q. It's different, though --

A. It is.

Q. -- than the laser cut mesh, isn't it?

A. It is a different method of cutting it.

Q. Now, if you also look further at column 29, and if you look at the "Failure Mode" on column 29 related to the laser cut mesh, you'll see that it says, "Mesh is too stiff." Do you see that?

A. Yes.

Q. So your company knew that as of this time, the TVT mesh that was laser cut could possibly come -- become too stiff and it could lead to damage to the urethra in a woman. Correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: That is what they listed, yes.

BY MR. CARTMELL:

Q. Because if you go over to the "Harm" listed, let's go over to that, specifically it states, "Damage to Urethra." Right?

A. Yes.

Q. Now, again, you use that same rabbit study that didn't even use laser cut mesh to be the control for that, the way you mitigated that harm. Correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: It's the study that the team used when they did this form, yes.

BY MR. CARTMELL:

Q. And you knew that, in fact, the laser cut mesh was actually stiffer than the TVT mesh. Right?

A. Not in the physiological range.

Q. Well, for example, for you, when you held it in your hand, you felt that it was stiffer?

A. Not in the physiological range.

Q. My question is specifically when you held the mesh in your hand, did you feel it was stiffer?

A. You'd have to define "stiffer," but --

Q. It felt more stiff?

MR. HUTCHINSON: Stop, hey, stop, Tom. The witness is trying to answer your question.

THE WITNESS: You would have to define "stiffness." It's -- but I personally feel that it's -- within the physiological range, it was the same.

MR. CARTMELL: Object and move to strike after the answer.

- - -

(Deposition Exhibit No. T-2183, E-mail chain, top one dated 11/1/2004, Bates stamped ETH.MESH.05548122 and

ETH.MESH.05548123, was marked for identification.)

- - -

BY MR. CARTMELL:

Q. I'm going to hand you what has been marked as 2183. It's an e-mail from you to doctors that you are consulting with related to the laser cut mesh.

And before I ask you about this specifically, it's true, Mr. Smith, that if a mesh is too stiff, then that can cause erosions and pain for women. Correct?

A. It could.

Q. And this was specifically your statement, if you look at the -- I believe it's the fourth paragraph down, we've got it outlined here, you state to these doctors who you are asking to consult related to the mesh, "You will also be evaluating our current TVT mesh (mechanically cut) and a new laser cut mesh that does not fray and has a stiffer feel."

Okay. So you personally felt like the laser cut mesh had a stiffer feel. Correct?

A. Beyond the physiological range, yes.

Q. The truth is that your company did

testing on the mesh and actually found that the elongation, what, was more or less with the laser cut mesh?

A. Beyond the physiological range, it was less, given a certain load.

Q. If the elongation of a mesh is less, then it will actually be stiffer. Correct?

A. Not necessarily stiffer, as typically defined in the other direction.

- - -

(Deposition Exhibit No. T-2184, Memo dated December 14, 2004, Bates stamped ETH.MESH.01809080 and ETH.MESH.01809081, was marked for identification.)

- - -

BY MR. CARTMELL:

Q. Let me hand you what's been marked as 2184.

MR. HUTCHINSON: Counsel, do you have a copy?

MR. CARTMELL: I just gave them to you.

BY MR. CARTMELL:

Q. Doctor, this is a memo to you and Paul Parisi.

Who is Paul Parisi?

A. I'm sorry, you just called me "doctor."

Q. I'm sorry. Strike that. Sorry, strike that. You're not a doctor. Sorry. I'll start over.

Mr. Smith, this is a memo to you and Paul Parisi.

Who is Paul Parisi?

A. Paul Parisi was in marketing at the time, I believe.

Q. And it's from Becky Leibowitz.

Who is she?

A. She was part of the CPC or product characterization group.

Q. It's regarding a "Comparison of Laser-Cut" Mesh "and Machine-Cut TVT Mesh to Meshes from Competitive Devices." Right?

A. Yes, I believe it is.

Q. So it sounds like you looked at your TVT mesh that was machine cut.

And is it true that that is the mesh that had particles that would be lost or come off the product and it would fray?

A. If we could recall -- call it

mechanically cut rather than machine cut, I would agree, yes.

Q. I'm sorry, okay.

Then you compared that with laser cut mesh that your risk analysis said could be stiffer. Correct?

A. The risk analysis said that if it was too stiff, it might be a problem.

Q. And this was actually the results of a study, if you look at the results down there. It states, "The average load at one-fourth inch intervals of elongation, up to 1 inch (20%) of elongation was calculated for both groups of TVT mesh and is plotted below in the Figure along with several meshes from competitor devices. At 1 inch of stretch, the laser-cut TVT mesh was about three times stiffer than the machine-cut TVT mesh." Right?

A. That was beyond the physiological range.

MR. CARTMELL: Object and move to strike the answer. And I'll ask you to answer the question yes or no.

BY MR. CARTMELL:

Q. The laser cut mesh that was measured